EUROPEAN
COMMISSION

Brussels, 10.2.2023
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COMMISSION IMPLEMENTING DECISION

of 10.2.2023

granting an authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council to Husqvarna AB for a use of chromium trioxide

(Only the English text is authentic)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1], and in particular Article 64(8) thereof,

Whereas:

(1) Chromium trioxide is listed in Annex XIV to Regulation (EC) No 1907/2006 and uses of that substance are subject to the authorisation requirement in Article 56(1), point (a), of that Regulation.

(2) On 10 August 2020, Husqvarna AB ('the applicant') submitted an application in accordance with Article 62 of Regulation (EC) No 1907/2006 for authorisation for a use of chromium trioxide. The use for which authorisation was sought is the industrial use of a mixture containing chromium trioxide in functional chrome plating of saw chain cutter links in order to meet stay-sharp and durability requirements for use with chainsaws.

(3) On 31 August 2021, the Commission received the opinions on the application adopted by the Committee for Risk Assessment (RAC) and by the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency[2] and sent to it pursuant to Article 64(5), second subparagraph, of Regulation (EC) No 1907/2006.

(4) RAC concluded in its opinion that it is not possible to determine a derived no-effect level for the carcinogenic properties of chromium trioxide in accordance with Section 6.4 of Annex I to Regulation (EC) No 1907/2006 and that therefore chromium trioxide is a substance for which it is not possible to determine a threshold for the purposes of Article 60(3), point (a), of that Regulation. As a result, Article 60(2) of Regulation (EC) No 1907/2006 does not apply to that substance and an authorisation may therefore only be granted with respect to that substance under paragraph 4 of that Article.

[1] OJ L 396, 30.12.2006, p. 1.

[2] https://echa.europa.eu/documents/10162/ca028483-5d7a-b974-efd4-57d730f52c1c

(5) In its opinion, RAC concluded that the risk management measures and operational conditions described in the application, and further detailed by the applicant at RAC's request, are appropriate and effective to limit the risk, both to workers and to members of the general population who could potentially be exposed to chromium trioxide via the environment, posed by the use of chromium trioxide described in the application. However, in order to address some shortcomings on the representativeness of occupational exposure and environmental release measurements and to provide information on the trends in exposure and emissions during the authorisation period, RAC recommended monitoring programmes for both occupational exposure to, and environmental release of, hexavalent chromium (Cr(VI)), which is the hazardous component of chromium trioxide. Having evaluated RAC's assessment, the Commission agrees with that conclusion and those recommendations.

(6) In its opinion, SEAC concluded that it has no substantial reservations on the quantitative and qualitative elements of the applicant's assessment of the benefits and the monetised risks to human health associated with the continued use of the substance. Taking into account SEAC's assessment of the socio-economic analysis, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, the estimated monetised risk of cancer associated with the continued use in the order of thousands of euro per year, the estimated monetised socio-economic benefits of continued use due to avoided job losses and relocation costs in the order of millions of euro per year, as well as the qualitatively assessed additional socio-economic benefits of the continued use due to avoided indirect job losses, the Commission concludes that the applicant has demonstrated that the socio-economic benefits of continued use of chromium trioxide outweigh the risk to human health and the environment arising from that use.

(7) A suitable alternative should be safer, available, and technically and economically feasible. Where suitable alternatives are available in the Union, but not technically or economically feasible for the applicant or its downstream users, the applicant is required to submit a substitution plan. An alternative that provides the functionality and level of technical performance necessary for the use applied for should be considered to be technically feasible. Certain potential alternatives may provide the functionality but at some loss to performance or in a manner that involves technical compromises that would impair the functionality. In such cases, unless justified by particular circumstances, the Commission should not consider a potential alternative to be technically feasible for the applicant where the applicant has demonstrated that it or its downstream users are not able to accommodate such losses to performance or technical compromises by applying a reasonable additional effort, taking into account the circumstances of the case.

(8) In its opinion, SEAC concluded that there were no suitable alternatives available for the applicant at the time of adoption of its opinion. The Commission, having evaluated SEAC's assessment and relevant information available, notes that the identified alternatives to chromium trioxide provide the overall functionality and are commercially available in the Union, but do not ensure yet the necessary performance in terms of the key functionalities of grindability of the cutting edge and stay-sharp time, requiring further research and development optimisation to comply with the applicant's quality standards. Therefore, the Commission considers that the identified alternatives cannot yet be considered technically feasible and agrees with SEAC's conclusion that there are no suitable alternatives for the applicant, but concludes that suitable alternatives are available in the Union.

(9) In its opinion, SEAC further concluded that the substitution plan submitted by the applicant is credible and consistent with the analysis of alternatives and the socio-economic analysis. The Commission, having evaluated SEAC's assessment, concurs with that conclusion. Therefore, the Commission considers that the applicant has discharged its burden of proof in demonstrating the absence of suitable alternative substances or technologies for the applicant.

(10) Therefore, having regard to the conditions laid down in Article 60(4) of Regulation (EC) No 1907/2006, it is appropriate to authorise the use of chromium trioxide described in the application, provided that the risk management measures and operational conditions described in the chemical safety report are fully applied.

(11) The Commission has based its assessment on all relevant scientific evidence currently available, as assessed by RAC and SEAC, and, after having carried out a detailed examination, based its conclusions on a sufficient amount of material and reliable information allowing it to conclude. Nevertheless, additional scientific evidence would allow the Commission to perform its assessment on a more robust or broad evidentiary basis in the future. Hence, it is appropriate to require additional exposure and emission information to be generated.

(12) SEAC recommended in its opinion that the review period referred to in Article 60(9), point (e), of Regulation (EC) No 1907/2006 be set until the end of 2032. The Commission agrees with that recommendation, taking into account the relevant elements from RAC's and SEAC's assessments and, in particular, RAC's conclusion that the risk management measures and operational conditions are appropriate and effective to limit the risk, SEAC's conclusions on the monetised risk to human health and on the socio-economic benefits of the continued use of the substance, the applicant's long investment cycle and its ongoing research efforts.

(13) The language used to describe the risk management measures and operational conditions in the application for authorisation may be different from the official language of the Member State where the use takes place. Therefore, in order to facilitate supervision and enforcement of compliance with the authorisation, it is appropriate to require the authorisation holder to submit, upon request, a brief summary of those risk management measures and operational conditions to the competent authority of that Member State in an official language of that Member State.

(14) This Decision does not affect the obligation of the authorisation holder to ensure that a use of a substance does not adversely affect human health or the environment, having regard to the principle set out in Article 1(3) of Regulation (EC) No 1907/2006. Furthermore, this Decision does not affect the obligation of the authorisation holder under Article 60(10) of that Regulation to ensure that the exposure is reduced to as low a level as is technically and practically possible or the obligation of the employer under Article 4(1) and Article 5, of Directive 2004/37/EC of the European Parliament and of the Council[3] to reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, in so far as is technically possible, and to prevent workers' exposure to a risk to their health or safety. This Decision does not affect the application of Union law in the area of health and safety at work, in particular Council

[3] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

Directives 89/391/EEC[4], 92/85/EEC[5], 94/33/EC[6] and 98/24/EC[7] and Directive 2004/37/EC, or any national binding occupational limit values which may be stricter than the applicable limit values under Union law.

(15) This Decision does not affect any obligation to comply with emission limit values or other requirements set in accordance with Directive 2008/50/EC of the European Parliament and of the Council[8] or Directive 2010/75/EU of the European Parliament and of the Council[9], nor any obligation to comply with emission limit values set to achieve compliance with the environmental quality standards established by Member States in accordance with Directive 2000/60/EC of the European Parliament and of the Council[10] or the environmental quality standards established in Directive 2008/105/EC of the European Parliament and of the Council[11]. Compliance with the provisions of this Decision does not necessarily imply compliance with any emission limit values or environmental quality standards under any other provisions of Union law, which may include further or more onerous requirements.

(16) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

An authorisation is hereby granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of chromium trioxide (EC No 215-607-8; CAS No 1333-82-0):

Authorisation number	Authorised use
REACH/23/2/0	Industrial use of a mixture containing chromium trioxide in functional chrome plating of saw chain cutter links in order to meet stay-sharp and durability requirements for use with chainsaws

[4] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

[5] Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 348, 28.11.1992, p. 1).

[6] Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work (OJ L 216, 20.8.1994, p. 12).

[7] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

[8] Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe (OJ L 152, 11.6.2008, p. 1).

[9] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

[10] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

[11] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

The authorisation is granted subject to the risk management measures and operational conditions described in the chemical safety report[12].

Article 2

1. The review period shall expire on 31 December 2032.

2. The authorisation shall cease to be valid on 31 December 2032 if the authorisation holder has not submitted the review report in accordance with Article 61(1) of Regulation (EC) No 1907/2006 by 30 June 2031.

Article 3

1. The monitoring arrangements set out in paragraphs 2 to 6 shall apply.

2. The authorisation holder shall carry out a monitoring programme measuring occupational exposure to hexavalent chromium (Cr(VI)). The measurements shall:

   (a) be conducted at least annually or more frequently if a significant increase of chromium trioxide consumption takes place on site and the frequency of the measurements shall be sufficient to capture any potential increase in inhalation exposure of workers to Cr(VI);

   (b) be based on relevant standard methodologies and protocols;

   (c) ensure a sufficiently low limit of quantification;

   (d) comprise personal and/or static inhalation exposure sampling;

   (e) be representative of all the tasks with possible inhalation exposure to Cr(VI), the operational conditions and risk management measures for each of these tasks, and of the total number of workers who are potentially exposed;

   (f) be recorded so as to include contextual information about the tasks performed during sampling.

3. The authorisation holder shall carry out a monitoring programme for measuring the environmental releases of Cr(VI). The measurements shall:

   (a) comprise air emission measurements to be carried out at least annually or more frequently if a significant increase of chromium trioxide consumption takes place on site and the frequency of the measurements should be sufficient to capture any potential increase in emissions of Cr(VI);

   (b) be based on relevant standard methodologies or protocols;

   (c) be representative of the operational conditions and risk management measures used at the site where the authorised use takes place;

   (d) ensure a sufficiently low limit of quantification;

   (e) be recorded so as to include contextual information associated with each set of measurements.

4. The authorisation holder shall use the information gathered via the measurements referred to in paragraphs 2 and 3 and related contextual information to confirm and

[12] https://ec.europa.eu/docsroom/documents/47494

review, at least annually, the effectiveness of operational conditions and risk management measures in place. If needed, the authorisation holder shall introduce measures to further reduce occupational exposure to Cr(VI), in accordance with the hierarchy of control principles, and emissions into the environment of Cr(VI), to as low a level as technically and practically possible.

5. The authorisation holder shall document and maintain the information gathered via the monitoring programmes referred to in paragraphs 2 and 3, including the contextual information associated with each set of measurements, as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 4. The authorisation holder shall make that information, including pseudonymised biomonitoring results, available, upon request, to the competent authority of the Member State where the authorised use takes place.

6. The authorisation holder shall document the steps taken to substitute chromium trioxide in accordance with the substitution plan, including information on any deviations from the initial plan and on contingency measures taken, and shall make that documentation available, upon request, to the competent authority of the Member State where the authorised use takes place.

7. If the authorisation holder submits a review report as referred to in Article 61(1) of Regulation (EC) No 1907/2006, it shall include the information referred to in paragraph 5 and 6.

Article 4

Upon request, the authorisation holder shall submit a brief summary of the applicable risk management measures and operational conditions described in the chemical safety report to the competent authority of the Member State where the authorised use takes place in an official language of that Member State.

Article 5

This Decision is addressed to Husqvarna AB, EM-OFPM/ErK, 56182, Huskvarna, Sweden.

Done at Brussels, 10.2.2023

For the Commission
Thierry BRETON
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION